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b) treating said test nucleic acid substrate under conditions such that said substrate forms one or more cleavage structures, said cleavage structures comprising one or more intra-strand secondary structures, wherein a primer is not annealed to said cleavage structures;

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c) reacting said cleavage means with said cleavage [intra-strand secondary] structures so that one or more test cleavage products are produced; and

d) comparing said test cleavage products to said control cleavage products.

4. In claim 4, line 2, "Cleavase™" has been deleted.

5. In claim 6, line 2, "comprising has been deleted and --consisting of-- has been inserted therefore.

6. In claim 7, line 1, after "nucleic acid", --substrate-- has been inserted.

7. In claim 8, line 1, after "nucleic acid", --substrate-- has been inserted.

8. In claim 9, line 1, after "nucleic acid", --substrate-- has been inserted.

9. In claim 10, line 1, after "nucleic acid", --substrate-- has been inserted.

10. In claim 11, line 2, "said" has been deleted, and --the-- has been inserted therefore, and after "nucleic acid" --substrate-- has been inserted, and in line 4, "said" has been deleted, and --the-- has been inserted therefore, and after "nucleic acid" --substrate-- has been inserted.

11. In claim 12, line 1, "said" has been deleted, and --the-- has been inserted therefore, and after "nucleic acid" --substrate-- has been inserted.

12. In claim 13, line 2, --test-- has been inserted before "cleavage".

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13. In claim 14, after "said" --reference-- has been inserted, and "comprises bacteria" has been deleted and --is a bacterium-- has been inserted therefore.

14. <sup>14</sup> (Once amended) The method of Claim <sup>13</sup> 14 wherein [said bacteria are] the bacterium is selected from the group [comprising] consisting of members of the genera *Campylobacter, Escherichia, Mycobacterium, Salmonella, Shigella* and *Staphylococcus*.

15. In claim 17, after "said" --reference-- has been inserted, and "comprises bacteria" has been deleted and --is a bacterium-- has been inserted therefore.

16. In claim 18, line 2 "comprising" has been deleted and --consisting of-- has been inserted therefore.

17. <sup>18</sup> (Three times amended) A method for [treating] cleaving nucleic acid, comprising the steps of:

- a) extracting nucleic acid from a sample suspected of containing one or more microorganisms; and
- b) contacting [said] the extracted nucleic acid with an enzymatic cleavage means under conditions such that [said] the extracted nucleic acid forms one or more cleavage structures, said cleavage structures comprising one or more intra-strand secondary structures, wherein a primer is not annealed to said cleavage structures, and [said] the cleavage means cleaves said cleavage [intra-strand secondary] structures to produce a plurality of cleavage products.

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18. In claim 22, line 1, "said" has been deleted and --the-- has been inserted therefore, and in line 3, "derived" has been deleted and --the-- has been inserted after "from".
19. In claim 24, line 1, "said" has been deleted and --the-- has been inserted therefore.
20. In claim 26, line 2 "comprising" has been deleted and --consisting of-- has been inserted therefore.
21. In claim 27, line 3, "derived" has been deleted.
22. In claim 32, line 2, "Cleavase<sup>TM</sup>" has been deleted.
23. In claim 33, line 1, before "nucleic acid" --extracted-- has been inserted.
24. In claim 34, line 1, before "nucleic acid" --extracted-- has been inserted.
25. In claim 35, line 1, before "nucleic acid" --extracted-- has been inserted.
26. In claim 36, line 1, before "nucleic acid" --extracted-- has been inserted.
27. In claim 37, line 1, "said treating" has been deleted and --the cleaving-- has been inserted therefore, and in line 4, "said" has been deleted and --the-- has been inserted therefore, and in line 5, "said" has been deleted and --the-- has been inserted therefore.
28. In claim 38, line 1, "said" has been deleted and --the-- has been inserted therefore.
29. In claim 39, line 1, "said" has been deleted and --the-- has been inserted therefore, and "comprises bacteria" has been deleted and --is a bacterium-- has been inserted therefore.
30. In claim 42, line 1, "said" has been deleted and --the-- has been inserted therefore, and "comprises" has been deleted and --is a-- has been inserted therefore.

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31. In claim 43, line 1, "said" has been deleted and --the-- has been inserted therefore, and in line 2 "comprising" has been deleted and --consisting of-- has been inserted therefore.

32. <sup>44</sup> (Three times amended) A method of producing cleavage products comprising the steps of:

a) providing:

i) an enzymatic cleavage means in a solution comprising manganese;

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and

ii) a nucleic acid substrate containing microbial gene sequences;

b) treating said nucleic acid substrate with increased temperature under conditions such that single-stranded is produced;

c) reducing said temperature under conditions such that said single-stranded substrate forms one or more cleavage structures, said cleavage structures comprising one or more intra-strand secondary structures, wherein a primer is not annealed to said cleavage structures;

c) reacting said enzymatic cleavage means with said cleavage [intra-strand secondary] structures so that one or more test cleavage products are produced; and

d) detecting said one or more cleavage products.

33. In claim 46, line 2, "Cleavase<sup>TM</sup>" has been deleted.

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34. In claim 48, line 2 "comprising" has been deleted and --consisting of-- has been inserted therefore.

35. In claim 49, line 1, after "nucleic acid", --substrate-- has been inserted.

C4 36. ~~50~~<sup>48</sup> (Once amended) The method of claim ~~44~~<sup>42</sup>, wherein said [microorganism comprises] microbial gene sequences are from bacteria.

37. In claim 51, line 2 "comprising" has been deleted and --consisting of-- has been inserted therefore.

C5 38. ~~51~~<sup>48</sup> (Once amended) The method of claim ~~44~~<sup>42</sup>, wherein said [microorganism comprises] microbial gene sequences are from virus.

39. In claim 54, line 2 "comprising" has been deleted and --consisting of-- has been inserted therefore.

### Conclusion

40. Certain papers related to this application are *welcomed* to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Friday from 8:30 AM to 5:00 PM, EST. If attempts to reach the

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examiner by telephone are unsuccessful, the examiner's supervisor, Robert Schwartzman can be reached at (703) 308-7307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Zeta Adams, whose telephone number is (703) 305-3291.

William Sandals, Ph.D.

Examiner

August 10, 2001



TERRY MCKELVEY  
PRIMARY EXAMINER

